

REMARKS

Claims 1 through 23 and new Claims 24 through 26 are pending in the application.

Claim 1 has been amended to reflect that the condensed tannins are denatured. Support for this amendment can be found in the Application as filed, for example on Page 4, line 25 through 30 in combination with Page 6, line 1.

Claim 1 has also been amended to remove the term “pinitol”, which is a specific form of cyclitol.

Claim 1 has also been amended to correct informalities.

Claims 2 through 10 have been amended to correct informalities.

Claim 11 has been amended to reflect that the recited fruits are carob fruits. Support for this amendment can be found in the Application as filed, for example on Page 4, lines 10 through 20.

Claim 11 has further been amended to reflect that whole fruit is crushed and that the crushing provides carob seed and carob pulp. Support for this amendment can be found in the Application as filed, for example on Page 4, lines 15 through 25.

Claim 11 has also been amended to remove the term “kibbled.”

Claim 11 has additionally been amended to reflect that toasting is performed on the separated carob pulp. Support for this amendment can be found in the Application as filed, for example on Page 4, lines 20 through 30.

Claim 11 has been amended to reflect that the extraction is performed on the toasted carob pulp with water or solvent, and further that the recited extraction removes sugars and water-soluble tannins. Support for this amendment can be found in the Application as filed, for example on Page 4, lines 31 through 32.

Claim 11 has also been amended to reflect that the separation step separates the soluble components out of the extracted carob pulp to produce insoluble residue. Support for this amendment can be found in the Application as filed, for example on Page 5, lines 8 through 12.

Claim 11 has further been amended to reflect that the milling step is performed on the insoluble residue and results in a powder comprising particles in which 90% of said particles exhibit a particle size below 250 μm . Support for this amendment can be found in the Application as filed, for example on Page 5, lines 11 through 14.

Claim 11 has additionally been amended to reflect that the separating step removes water from the insoluble residue. Support for this amendment can be found in the Application as filed, for example on Page 5, lines 8 through 10 and lines 21 through 22.

Claim 11 has been amended to reflect that the drying step is performed on the milled insoluble residue and results in a water content of below 8 % by weight. Support for this amendment can be found in the Application as filed, for example on Page 5, line 23 in conjunction with Page 3, line 14.

Claim 11 has also been amended to reflect that the dried product is subjected to sieving. Support for this amendment can be found in the Application as filed, for example on Page 5, line 27.

Claim 11 has additionally been amended to remove informalities.

Claim 12 has been amended to remove informalities and to recite “carob fruit” in conformance with Claim 11. Support for this amendment can be found in the Application as filed.

Claim 13 has been amended to positively recite that the temperature is associated with toasting and further to remove informalities. Support for this amendment can be found in the Application as filed, for example on Page 4, lines 25 through 30.

Claim 14 has been amended to remove informalities.

Claim 15 has been amended to positively recite that the time period is associated with toasting and further to remove informalities. Support for this amendment can be found in the Application as filed, for example on Page 4, lines 25 through 30.

Claim 16 has been amended to positively recite temperature and to further remove informalities. Support for this amendment can be found in the Application as filed, for example on Page 4, line 31 through Page 5, line 3.

Claim 17 has been amended to positively recite the use of water within the extraction step and to further remove informalities and parenthesis. Support for this amendment can be found in the Application as filed, for example on Page 4, line 31.

Claim 18 has been amended to remove informalities.

Claim 19 has been amended to remove informalities and further to reflect that in the advantageous embodiments of Claim 19 the particle size is below 150 μm . Support for this amendment can be found in the Application as filed, for example on Page 5, lines 11 through 15.

Claims 20 and 21 have been amended to remove informalities.

Claims 24 through 26 have been added to complete the record for examination and highlight particularly advantageous embodiments of the invention.

Claim 24 reflects advantageous inventive carob flour embodiments in which the cyclitol is pinitol.. Support for Claim 24 can be found in the Application-as-filed, for example in Claim 1 as-filed.

Claim 25 reflects advantageous carob flours which are toasted at temperatures ranging from 140 to 200 °C, and which further impart a greater drop in serum cholesterol than imparted by a comparable amount of natural carob fiber. Support for Claim 24 can be found in the Application-as-filed, for example in Claims 11 and 12 as-filed, as well as on Page 6, line 26 through Page 7, line 14.

Claim 26 reflects advantageous carob flours that include a total of three extractions, imparting a sugar content within the resulting carob flour of less than 10%. Support for Claim 26 can be found in the Application-as-filed, for example on Page 4, line 31 through Page 5, line 20.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Section 112 Rejections

Claim 1 through 23 stand rejected over the recitation "denatured carob flour." Applicants respectfully submit that sufficient support exists within the Application-as-filed for "denatured carob flour," such as on Page 6, lines 1 through 6. Applicants further respectfully submit that denatured carob is a term that is well understood by one skilled in the art to refer to carob which has been subjected to heat treatment sufficient to increase the polymerization of the naturally occurring condensed tannins. Support for this definition can be found in the Application-as-filed

on Page 3, line 30 through Page 4, line 2. The foregoing definition is further evidenced in cited United States Patent No. 5,043, 160 at Col. 2, lines 10 through 18.

Claim 11 stands rejected over the recitation in step "c" of "kibbled". The foregoing recitation has been removed from Claim 11. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claim 11 stands rejected over the recitation in "d" of "tasted." Applicants' Representative respectfully submit that the claim set included within the Preliminary Amendment of January 27, 2005 recites "toasted", as indicated on the PTO PAIR webpage under Mail Room Date 1-27-05.

Claim 11 further stands rejected over the recitations in steps "e," and "f," and "h," over what is extracted with what and what is separated. Claim 11 has been amended to reflect that the extraction is performed on the toasted carob pulp with water or solvent, and that the separation step separates the soluble components out of the extracted carob pulp to produce insoluble residue. As noted above, support for this amendment can be found in the Application-as-filed.

Claim 11 stands additionally rejected over the recitation in step "j" of "classifying". Claim 11 has been amended to remove the term "classifying." Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claim 11 stands rejected due to the presence of parenthesis. Claim 11 has been amended to remove the noted parenthesis. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claim 11(i) stands rejected over the recitation "below 8%." Claim 11 has been amended to reflect that the recited percentage refers to water content by weight. As noted above, support for this amendment can be found in the Application-as-filed. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claim 12 stands rejected for lack of antecedent basis for the term "carob pod". Claim 12 has been amended to recite "carob fruit" in conformance with Claim 11. As noted above, support for this amendment can be found in the Application as filed. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claim 13 stands rejected over the term "temperature." Claim 13 has been amended to positively recite that the temperature is associated with toasting and further to remove informalities. As noted above, support for this amendment can be found in the Application as filed. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claim 17 stands rejected over the term "water," and further for the parenthesis around "(wt./wt.)". Claim 17 has been amended to positively recite water and further to delete the noted parenthesis. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claim 19 stands rejected over the phrase "particles." Antecedent basis for the recited particles has been incorporated into independent Claim 11. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claim Objections

Claim 8 stands objected to over the misspelling of "tannins". Claim 8 has been amended to correct the foregoing misspelling. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

The Claimed Invention is Patentable in Light of the Art of Record

Claims 1 through 23 stand rejected over United States Patent No. 5,856,313 to Marco et al. in view of United States Patent No. 5,043,160 to Wursch and United States Patent No. 4,617,188 to Page et al.

It may be useful to briefly consider the invention before addressing the merits of the rejection.

There is considerable interest in developing dietary fiber products rich in polyphenols, due to the protective role of these substances against cardiovascular disease by reducing hypercholesterolemia and their effects on the efficacy of the intestinal translocation and the prevention of colonic cancer.

Tannins, such as contained in carob, are an example of such beneficial polyphenols. Carob contains two primary classes of tannins: soluble tannin and insoluble tannin (also referred to as condensed tannin).

Unfortunately, tannins, although providing significant health benefits, are extremely astringent. Consequently, sufficient dosages of tannin-derived polyphenols are currently not available for the treatment of chronic, degenerative diseases, because at the elevated dosages required the tannins are a strong astringent and have an antinutritional effect. In addition, natural carob includes significant amounts of sugar, which is also considered disadvantageous at the high dosages required for chronic, degenerative conditions.

Surprisingly, Applicants have found that carob fibers subjected to a combination of heat treatment, i.e. toasting, and subsequent extraction provide carob flour including highly advantageous tannin contents and acceptable levels of astringency, even at the dosages required to treat cholesterolemia.

Altogether unexpectedly, the inventive carob flour has a more pronounced effect on cholesterolemia than natural carob flour. Although not wishing to be bound by theory, Applicants hypothesize that the inventive carob flours may more effectively capture bile salts than natural carob flour. In that regard, the Examiner's attention is kindly directed to the Application-as-filed on Page 6, line 26 through Page 7, line 14. The health benefits associated

with toasted carob flour are especially surprising in light of the fact that the toasting of bread can lead to increased levels of benzopyrene, a known carcinogen.

Accordingly, the claims are directed to denatured carob flour including sugars in an amount of 2 to 15 % by weight and denatured condensed tannins in an amount of 25 to 55 % by weight.

In advantageous embodiments, the inventive carob flour includes sugar in an amount of between 3 to 10 % by weight, as recited in Claim 2.

The inventive flours are formed by processes incorporating a toasting step which denatures carob pulp at a temperature ranging from 130 °C to 200 °C. The toasted pulp is then extracted with water or solvent to remove sugars and water-soluble tannins; the insoluble residue separated, milled and sieved.

In advantageous embodiments, the inventive processes include a toasting process having a toasting temperature of between 140 and 150 °C, as recited in Claim 13.

In further advantageous embodiments, multiple extraction steps are performed, as reflected in Claims 20 and 26. Such multiple extraction steps provides denatured carob flours having as little as 10 wt% sugar, as further recited in new Claim 26.

The inventive toasted carob flours have been found to be extremely advantageous in treating hypercholesterolemia. For example, the inventive toasted carob fiber has been found to induce a lower serum cholesterol level than a comparable amount of natural carob fiber, as recited in new Claim 25.

The cited references do not teach or suggest the claimed invention.

US 313 is directed to natural carob fibers that are subjected to a single extraction with water and then dried. (US 313, Col. 2, line 28 – Col. 3, line, 34). US 313 expressly cautions that the pulp and extraction water must “contact for the minimum amount of time necessary.” (Col. 2, lines 37 – 40). In contrast to the recited tannin-rich products, the natural carob fibers of US 313 include only a modest amount of tannin, i.e. tannin in an amount ranging from 3 to 7 %. (US 313, Col. 3, lines 55 – 65). As correctly noted by the Examiner, US 313 further includes quite elevated amounts of lignin, i.e. from 50 to 65 % lignin. (US 13, Col. 3, lines 55 – 65).

Accordingly, US 313, directed to natural carob, does not teach or suggest the recited denatured carob flour, much less such denatured carob flour including denatured condensed tannins in an amount of 25 to 55 % by weight, and most certainly not flour further including lignin in an amount of 2 to 10% by weight.

And US 313 can not teach or suggest the recited toasting step, much less such toasting at temperatures of up to 200 °C, and most certainly not extracting such toasted carob pulp, as recited in Claim 11. Applicants respectfully submit the drying conditions of US 313 can not be imputed to the recited toasting step, as urged within the outstanding Office Action, as toasting and drying constitute significantly different processes, as discussed in greater detail below.

Nor does US 313 teach or suggest the advantageous toasting temperatures of between 140 and 150 °C, as recited in Claim 13.

US 313, merely disclosing a single extraction, likewise fails to teach or suggest inventive processes in which milled insoluble residue is subjected to multiple extractions and separations, as recited in Claim 20, much less that such multiple extraction steps would denatured carob flours having as little as 10 wt% sugar, as further recited in Claim 26. US 313 instead teaches away from such multiple extractions by expressly requiring minimum contact between the carob and extraction water.

US 313, directed to natural carob medicaments, clearly does not teach or suggest that the inventive toasted carob fiber induces a lower serum cholesterol level than a comparable amount of natural carob fiber, as recited in new Claim 25. As noted above, the health benefits associated with the toasting of carob fibers are surprising in light of conventional wisdom.

Applicants take this opportunity to respectfully submit that the claimed methods, in which the carob is toasted before the extraction process, are responsible for the recited elevated tannins. Carob fiber prior to extraction has a lower moisture content, and hence toasting prior to extraction allows for more precise temperature control, and thus greater control during tannin denaturing. In contrast, the modest amount of tannin in US 313 occurs because US 313 merely dries carob after extraction, without the recited toasting. This change in tannin level clearly evidences that toasting and drying constitute significantly different processes. Drying merely connotes the removal of water from a substance. Toasting connotes a physical change within the chemical composition of the substance itself, e.g. the partial degradation and polymerization of polyphenols within the carob, which may or may not be accompanied by drying. In this regard, the Examiner's attention is kindly directed to the Application-as-filed on Page 3, line 30 through Page 4, line 3 (discussing the effects of toasting on carob).

Accordingly, the claimed invention is patentable in light of US 313, considered either alone or in combination with the remaining art of record.

The secondary references do not cure the deficiencies in US 313.

US 160 is similarly directed to natural carob fibers. (Col. 1, lines 59 – 61). The carob flour of US 160 contains at least 20 % by weight of native tannins. (Col. 1, lines 62 – 65). US 160 expressly defines “native tannins” as tannins which have not been denatured by a heat or chemical treatment. (Col. 2, lines 10 – 12). Consequently, US 160 expressly requires that its carob must be dried under conditions to “avoid thermal denaturing of the water-insoluble tannins, i.e. at a temperature not exceeding 100 °C.” (Col. 2, lines 1 – 8). US 160 goes on to caution that when non-desugared carob pods are roasted, a Maillard reaction takes place which destroys the

structure of the tannins. (Col. 2, lines 12 – 15). In a first process embodiment, US 160 notes that its carob is pasturized at a temperature of 95 to 98 °C, and then dried at a temperature “not exceeding 100 °C.” US 160 repeats its caution that “[d]rying takes place under conditions which avoid thermal denaturing of the tannins.” (Col. 4, lines 13 – 15). In a second process embodiment, US 160 similarly discloses use of water at a maximum of 98 C, followed by drying at a maximum of 70 C. (Col. 4, lines 26 – 40). The initial working example US 160 states that “the temperature ... of the product does not exceed 90 °C.” (Col. 5, lines 8 – 9).

US 160 indicates that the ripe carob used as a starting material has a sugar content of about 50% by weight. (Col. 3, lines 44 – 47). Even in light of such elevated sugar content, US 160 nevertheless merely teaches a single step de-sugaring for its carob. (Col. 3, line 64 – Col. 4, line 33). US 160 further indicates that its natural carob product is more active, even in a 5 times smaller dose, than roasted carob flour in the treatment of diarrhea. (Col. 8, lines 11 – 13).

Accordingly, US 160, directed to natural carob, does not teach or suggest the recited denatured carob flour, much less such denatured carob flour including denatured condensed tannins in an amount of up to 55 % by weight.¹ US 160 instead strongly teaches away from the recited denaturing, as the astringent natural carob fiber of US 160 are required to impart its anti-diarrheal properties.² Applicants take this opportunity to respectfully submit that the anti-diarrhea carob products of US 160, lacking denatured tannin, similarly would not be expected to provide anti-hypercholesterolemic properties.

US 160 thus does not teach or suggest the recited toasting, and most certainly not the recited toasting at 130 to 200 °C, as recited in Claim 11. Applicants respectfully submit that such toasting would render US 160 unfit for its intended purpose as an anti-diarrheal.

¹ In contrast to the urgings of the Office Action, denatured carob flour is understood by one skilled in the art to refer to carob fiber containing denatured tannin. Nevertheless, Claim 1 has been amended to further recite the presence of denatured tannin.

² Applicants respectfully submit that astringent medicaments cause constriction of exposed tissue or mucous membranes. Hence the importance of natural carob to US 160.

US 160 likewise fails to teach or suggest the advantageous toasting temperatures of between 140 and 150 °C, as recited in Claim 13.

US 160, merely disclosing a single de-sugaring, also fails to teach or suggest inventive processes in which milled insoluble residue is subjected to multiple extractions and separations, as recited in Claim 20, much less that such multiple extraction steps would provide denatured carob flours having as little as 10 wt% sugar, as further recited in Claim 26.

And US 160, directed natural carob medicaments, most certainly does not teach or suggest that the inventive toasted carob fiber induces a lower serum cholesterol level than a comparable amount of natural carob fiber, as recited in new Claim 25. US 160 instead expressly teaches that its natural carob product is a 5 times more active medicament than roasted carob flour.

Accordingly, the claimed invention is patentable in light of US 160, considered either alone or in combination with the remaining art of record.

US 188 is directed to insecticides including borax and roasted carob, in which the carob serves as an attractant. The carob is introduced to provide natural sugar, with sweeter carobs preferred. (Col. 2, lines 21 – 24 and Col. 4, lines 3 - 5). The carob in US 188 is simply roasted and ground. (Col. 2, lines 61 – 64).

US 188 similarly does not teach or suggest the claimed invention.

US 188, whose carob is included to provide natural sugar, does not teach or suggest the inventive extracted carob flour including as little as 2 % by weight of sugar.

US 188 similarly does not teach or suggest the recited extracting step, as recited in Claim 11.

Nor does US 188 teach or suggest the advantageous extraction conditions of Claims 16 through 18.

And US 188 most certainly does not teach or suggest inventive processes in which milled insoluble residue is subjected to multiple extractions and separations, as recited in Claim 20, much less that such multiple extraction steps would provide denatured carob flours having as little as 10 wt% sugar, as further recited in Claim 26. In fact, US 188 strongly teaches away from such embodiments by instead requiring the presence of natural sugars that would be removed by such extractions.

US 188, directed insecticide, clearly does not teach or suggest that the inventive toasted carob fiber induces a lower serum cholesterol level than a comparable amount of natural carob fiber, as recited in new Claim 25.

Accordingly, the claimed invention is patentable in light of US 188, considered either alone or in combination with the remaining art of record.

There would have been no motivation to have combined US 313, US 160 and US 188. Applicants respectfully submit that merely because the references can be combined is not enough, there must still be a suggestion. MPEP 2143.01 (section citing Mills). US 313 and US 160 are directed to natural carob fiber medicaments. US 188 is directed to insecticide having a natural sweetener. These are altogether different fields of endeavor and issues solved.

Applicants respectfully submit that the Office Action is instead indulging in impermissible hindsight by merely picking and choosing elements from the prior art while disregarding others and using the instant specification as the guide for that selection process.

However, even if the cited references were combined (which Applicants submit should not be done), the claimed invention would not result.

The combination more specifically does not teach or suggest the recited denatured, extracted carob flour, much less such denatured carob flour including denatured condensed tannins in an amount of up to 55 % by weight, and sugar in amounts as low as 2 % by weight.

The combination likewise fails to teach or suggest inventive processes including both toasting and extraction steps, and most certainly not the recited toasting at up to 200 °C, as recited in Claim 11.

The combination likewise fails to teach or suggest inventive processes in which milled insoluble residue is subjected to multiple extractions and separations, as recited in Claim 20, much less that such multiple extraction steps would provide denatured carob flours having as little as 10 wt% sugar, as further recited in Claim 26.

And the combination most certainly does not teach or suggest that the inventive toasted carob fiber induces a lower serum cholesterol level than a comparable amount of natural carob fiber, as recited in Claim 25.

Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of US 313, US 160 and US 188, considered either alone or in combination.

Consideration of Previously Submitted Information Disclosure Statement

It is noted that an initialed copy of the PTO/SB/08B that was submitted with Applicants' Information Disclosure Statement filed March 1, 2005 has not been returned to Applicants' representative with the Office Action. Accordingly, it is requested that an initialed copy of the PTO/SB/08B form be forwarded to the undersigned with the next communication from the PTO.

In order to facilitate review of the references by the Examiner, a copy of the Information Disclosure Statement and the PTO/SB/08B form are attached hereto. Copies of the cited references were provided at the time of filing the original Information Disclosure Statement, and, therefore, no additional copies of the references are submitted herewith. Applicants will be

pleased to provide additional copies of the references upon the Examiner's request if it proves difficult to locate the original references.

CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 26 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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